**Determining the effects of systemic antibiotic therapy on obesity trends in patients with acne**

**Authors:**

Stephanie Chapman

Renee Domozych

Jessica Mounessa

Katie Sullivan

Robert Dellavalle

Lisa Schilling

Date: 16 August 2016

**Acknowledgements:**

**Disclosures:**

**Abbreviations:**

BMI Body mass index

1. **Abstract:**

This study aims to evaluate obesity risk in children and adolescents treated with systemic antibiotics for acne as compared to those treated with topical therapies only. A potential link between childhood and adolescent obesity and antibiotic use has recently been reported [26486756]. In this study we will analyze data from a distributed network using the OHDSI CohortMethod package.

**2. Rationale and background:**

Acne vulgaris is one of the most common inflammatory skin disorders, especially among adolescents. Quality of life is often affected in patients with acne, and various psychiatric comorbidities have been associated with acne vulgaris [27508953]. Side effects of topical and systemic acne therapy can be significant, and recent work suggests that oral antibiotic use in children and adolescents leads to increased weight gain and a greater body mass index as compared to those not exposed to antibiotic therapy [26486756]. This study aims to determine the long term effects of systemic antibiotic therapy in children and adolescents with acne. In this study, we will analyze data collected from the OHDSI CohortMethod package.

**3. Research questions:**

Systemic antibiotics are commonly prescribed for the treatment of moderate and severe acne as well as inflammatory acne resistant to topical therapies (<https://www.aad.org/practice-tools/quality-care/clinical-guidelines/acne/systemic-antibiotics>). The American Academy of Dermatology recommends tetracyclines, macrolides, and trimethoprim-sulfamethoxazole for the systemic management of acne in combination with a topical retinoid. Common side effects of antibiotic therapy include photosensitivity, GI upset, and drug eruptions. Recently, the use of antibiotics has also been associated with increased obesity in children and adolescents [26486756]. The goal of our study is to first: determine the top three most commonly prescribed systemic therapies for acne and the top three most commonly prescribed topical therapies for acne, and second: determine if antibiotic therapy in children and adolescents with acne contributes to increased obesity as compared to patients receiving topical therapies only. We will use BMI as a measure of obesity.

* Primary Hypothesis: Children and adolescents with acne treated with systemic antibiotics will have a greater body mass index (BMI) as compared to patients treated with topical therapies only.

**4. Objectives:**

Primary objective:

-Assess BMI in patients with acne treated with systemic antibiotics as compared to those treated with topical therapies only.

**5. Research Methods:**

**5.1 *Study Design***

5.2 Overview:

This study will be a retrospective, observational, cohort study.

The treatment cohort will be patients with acne treated with oral antibiotics. The comparator cohort will be patients with acne treated with topical agents only.

Adjustment for baseline confounders??? *How do we do this???*

***5.3 Study population***

To determine the top three most common systemic therapies for acne and the top three most common topical therapies for acne, all subjects in the database will be included who meet the following criteria:

* Diagnosis of acne
* Age 8-21 years

To determine if children and adolescents treated with systemic antibiotics have a greater BMI as compared to patients treated with topical agents only, all subjects in the database will be included who meet the following criteria:

* Exposure to systemic antibiotics or topical agents only
  + *What antibiotics? And what topical agents should be included?*
* Age 8-21 years

***5.4 Potential confounders***

* Comorbid medical condition
* Other systemic medical therapy
* BMI at or above the 85th percentile prior to initiation of treatment with systemic antibiotics

**6. Protection of human subjects:**

This study is using only de-identified data. Confidentiality of patient records will be maintained at all times. All study reports will contain aggregate data only and will not identify individual patients or physicians.

**7. Plans for disseminating and communicating study results:**

The study results will be posted on the OHDSI website after completion of the study. At least one paper describing the study and its results will be written and submitted for publication to a peer-reviewed scientific journal.

**References:**

1. PMID=27508953
2. PMID= 26486756